## REMARKS

This Response and Amendment is in Response to the non-Final Office Action mailed July 3, 2007 and the Interview Summary Record mailed on August 3, 2007 received in the above-captioned application.

## STATEMENT OF SUBSTANCE OF INTERVIEW

Applicants acknowledge the Interview and Summary Record thereof mailed on August 3, 2007. Based on review thereof Applicants believe that it contains an accurate description of the entire substance of the interview. Applicants further note that the phrases indicated to be indefinite therein have been amended as suggested by the Examiner. It is Applicants' understanding from theinterview and the record thereof is that the amendments made herein will avoid any additional rejection of these claims under 35 USC 112 not already contained in the July 3, 2007 Office Action. Particularly, it will avoid a new indefiniteness rejection of Claims 27, 29, 31, 44, 48, 52, 54, 56, 58, 67 and 71 concerning the specific phrases recited in the Interview Summary to be unclear as these phrases urged to be indefinite or incomplete have been amended precisely as suggested by the Examiner in the Interview Summary Record.

Turning now to the non-final Office Action, Claims 27, 29, 31-33, 35-40, 44, 48-52, 54, 56-64, 67, and 71-76 were rejected therein based on 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed to the extent it is applicable to the claims as amended and in view of the following remarks.

The Examiner has objected to the claims of the invention for use of the term "prosthetic device" considering the term to be indefinite. The Examiner suggests amending the allegedly objectionable term to instead read "endoprosthesis". This amendment has been made in an effort to expedite allowance. However, Applicants maintain that the term prosthetic device is definite and would be readily understood by an ordinary skilled artisan in view of the teachings of this application. It should be understood that Applicants in no way acquiesce that the claims based on this amendment should be construed to be limited to a device when acting as an endoprosthesis. Particularly, the claim are intended as is clear from the teachings of the specification to cover the subject inventive product prior to when it enters the body, such as when present in a syringe, or

other dispensing or storage unit. The term "prosthetic device" does not impart a definition of the subject matter of the invention which is site specific, i.e. in the body or outside the body. Similarly, the term "endoprosthesis" is to be construed similarly, i.e. not limited to it being located within the body but also as a material for sale and distribution that is suitable for the recited intended use, i.e., it is injectable into soft tissue.

The Examiner has also objected to claims 75 and 76 for allegedly being indefinite because the terms "x" and "y" are not defined in these claims. These dependent claims refer to $(C_3H_5NO)_x(C_7H_{10}N_2O_2)_y$. The Examiner suggests amending these claims so as to define "x" and "y" as being in a molar ratio of 150 to 1 to 1000 to 1. Applicants advise that the Examniner's suggestion has been adopted.

Also, as noted above, subsequent to the Office Action, the Examiner informed Applicants in an interview on August 3, 2007 that the Quality Assurance Department upon review of the subject claims also requested, the following amendments::

- amending "monomeric units" in claims 27 and 52 to "monomers of acrylamide and N,N'-methylene bis-acrylamide"

  amending claims 33 and 58 so as to define the upper limit "less than 3.5%".

As can be seen from the Claim Listing contained herein these changes have been made without prejudice in order to expedite grant of this application.

Based on the foregoing withdrawal of the rejection of Claims 27, 29, 31-33, 35-40, 44, 48-52, 54, 56-64, 67, and 71-76 based on 35 U.S.C. § 112, second paragraph is respectfully requested..

The Examiner has also newly raised a provisional double patenting rejection of Claim 1 based on Claim 1 of copending US Serial No. 09/938,670. The Examiner asserts that the present claimed invention as set forth in claim 1 which is directed to "a prosthetic devise for a soft tissue augmentation" is not patentably distinct over the product recited in Claim 1 of US Serial No. 09/938,670 which is directed to "a bio-stable hydrogel for use as an endoprosthesis". At the outset it is noted that Claim 1 has been amended to now recite "an endoprosthesis for soft tissue augmentation". In addition, Applicants are submitting with this Amendment Reply a Terminal Disclaimer in order to overcome this provisional double patenting rejection.

The Examiner has also raised a new rejection of Claims 27, 562, 60-62, 72, and 75-76 as allegedly being unpatentable under 35 USC 103 on the basis that these claims are obvious over the teachings of newly cited EP 0 248 544 which names National Research Development Corp. as Applicant and Anis as the inventor. This rejection is respectfully traversed.

The newly cited EP document relates to a polyacrylamide based material used to elevate the proximal urethra from the pelvic floor and thereby restore its capability for response to intra-abdominal pressure. The device is secured and positioned by sutures and has a fixed size sutures; can be replaced by other tethering mechanisms. Conversely, the claims of the present invention define an injectable material having a complex viscosity of 2 to 100 Pas.

Contrary to the Office Action, the selection of complex viscosity is not a mere optimization of this property of the endoprosthesis, specific to the body area being filled, but instead is a feature of which has substantial practical implications in that it is now injectable (which is also a claimed feature) and does not have the draw-backs of requiring secure attachment by use of sutures or other tethering devices. It is clear that the device in the prior art document is solid in that it has a fixed size and shape with edge portions, which can be used to localise reinforcements by embedding other material in order to secure the device. It is clear that the Annis material is solid as it possesses a "body" with a defined shape and size (not a fluid which has an undefined structure) , and is clear from column 2, lines 57-61 wherein they refer to its preferable "kidney shape typically 5x3x1 cms, although it may be appropriate to provide other sizes". Clearly, based at least on these recitations the Annis material is a solid and does not and can not possess the fluid viscosity properties of the injectable hydrogel used in the present invention. Rather, it is a solid.

It also should be noted that the complex viscosity of polyacrylamide, which is fluid in the present invention and solid in Annis, is not an inherent feature of its solid weight content.

Also, based thereon, the present invention has the advantage over the cited document in that it is injectable, thereby not requiring surgical operations. This is not a mere optimization compared to Annis but rather a not-obvious conceptual change to the teaching of Annis which allows it to be administered by a different, more practical means (injection). . The injectable nature of the gel renders the medical procedures dramatically less invasive. This advantage is not taught by Annis.

Furthermore, an injectable material is further advantageous vis-à-vis the prior art solid material disclosed by Annis in that it facilitates an adjustment of the amount of material utilized during the medical intervention rather than requiring prediction and possible correction when

utilizing a solid material. Additionally the prosthetic device of the present invention is further an improvement over Annis in the fact that it can be more readily be held in place not by sutures, tethers or other mechanical implements, but rather by cellular growth of adjacent tissues. This is a further significant advantage of the invention over Annis which is not mere optimization.

Perhaps most significantly, the injectable nature of the gel is surprisingly suitable as an endoprosthesis at the defined solid weight content and viscosity. Neither Annis nor any of the prior art of record suggest that a polyacrylamide based hydrogel with such a low solid weight content can be made to be both injectable with the defined complex viscosity and yet still be suitable as a prosthetic device.

Also, Applicants note the Examiner's acknowledgement of the Information Disclosure Statement submitted on June 13, 207. Applicants again note that a previous Office Action stated, "No record could be found for an IDS filed 06/25/2005 and a copy of the postcard receipt of fax transmission will be required." The Supplemental Information Disclosure Statement which was filed on June 20, 2005 with a Petition for Withdrawal From Issue Under 37 C.F.R. § 1.313 and a Request for Continued Examination provided a copy of the documents cited in the afore-mentioned IDS and provide as well the date-stamped postcard indicating receipt of the documents in the USPTO are submitted herewith. Applicants again respectfully request the return of a copy of the Form PTO-1449 with the Examiner's initials in the left column in accordance with M.P.E.P. § 609.

## CONCLUSION

For at least the reasons stated above, claims 27, 29, 31-33, 35-40, 44, 48-52, 54, 56-64, 67, and 71-76 are in condition for allowance. Accordingly, Applicant respectfully requests that the Application be allowed and passed to issue.

In the event any outstanding issues remain, Applicant would appreciate the courtesy of a telephone call to Applicant's undersigned representative to resolve such issues in an expeditious manner.

The Commissioner is hereby authorized to charge Deposit Account No. 50-0206 in the amount of $250.00 for the one-month extension of time fee and terminal disclaimer fee. However, if the U.S. Patent and Trademark Office determines that any variance with the amount authorized above, the Commissioner is authorized to credit or debit any such variance to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: **October 10, 2007**

By: 
Robin L. Teskin
Registration No. 35,030

Hunton & Williams LLP
Intellectual Property Department
1900 K Street, N.W.
Suite 1200
Washington, D.C. 20006-1109
Ph. (202) 955-1500
Fax (202) 778-2201